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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,370	05/04/2001	Shawn R. Feaster	0207-0003P	6779

7590 11/14/2002

Office of the Staff Judge Advocate  
U.S. Army Medical Research and Materiel Command  
ATTN: MCMR-JA (Ms. Elizabeth Arwine)  
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Fort Detrick, MD 21702-5012

[REDACTED] EXAMINER

GUO, LYNDA T

[REDACTED] ART UNIT

[REDACTED] PAPER NUMBER

1651

DATE MAILED: 11/14/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/848,370	FEASTER ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Lynda T Guo	1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 04 May 2001.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-37 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) \_\_\_\_\_ is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) 1-37 are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)  The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

## **DETAILED ACTION**

### ***Status of the Application***

The IDS PTO-1449 (Paper No. 4) received on 03 October 2001 has been entered.

Claims 1-37 are pending and subject to restriction requirements in the present Application.

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-9, drawn to an assay for detecting, measuring or monitoring the activity or concentration of a protein, classified in class 435, subclass 7.1.
  - II. Claims 10-22, drawn to an assay for detecting, measuring or monitoring the activity or concentration of acetylcholinesterase and/or butyrylcholinesterase, classified in class 435, subclass 20.
  - III. Claim 23, drawn to a method of detecting or confirming whether a subject was exposed to an agent, classified in class 435, subclass 20.
  - IV. Claim 24, drawn to a method of determining the identity of an agent, classified in class 435, subclass 20.
  - V. Claim 25, drawn to a method of determining the efficacy or monitoring the progress of a treatment regime, classified in class 435, subclass 20.
  - VI. Claims 26 and 30, drawn to a method of determining whether a subject suffers from drug sensitivity or a disease, classified in class 435, subclass 20.
  - VII. Claim 27, drawn to a method of measuring the concentration of red blood cells in a subject, classified in class 435, subclass 20.

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- VIII. Claim 28, drawn to a method of screening for a candidate compound, classified in class 435, subclass 20.
- IX. Claim 29, drawn to a device for detecting, measuring or monitoring the activities or concentrations of acetylcholinesterase and/or butyrylcholinesterase, classified in class 435, subclass 287.1.
- X. Claims 31-34, drawn to a kit for detecting, measuring or monitoring the activities or concentrations of acetylcholinesterase and/or butyrylcholinesterase, classified in class 435, subclass 975.
- XI. Claim 35, drawn to a biosensor, classified in class 435, subclass 287.9.
- XII. Claims 36 and 37, drawn to a database of sensitivity coefficients, classified in class 707, subclass 1.

The inventions are distinct, each from the other because of the following reasons:

- 2. The methods of Inventions I-VIII are each different and distinct. They are different and patentably distinct methods because they involve different method steps, starting materials, reagents, and/or reaction conditions and/or produce different products or results.
- 3. The methods of Inventions I-VIII and the devices and kit of Inventions IX-XI are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case there are 3 different apparatus available (Inventions IX-XI) that can be used to practice many different methods (Inventions I-VIII).

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4. The kit of Invention X and the devices of Invention IX and XI are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because there are many devices known in the art that can be used to measure reaction rate (e.g. spectrophotometer). The subcombinations have separate utility such as to measure the activities of enzymes and proteins, other than what is claimed in the present Application

5. The devices of Inventions IX and XI are each different and distinct. They are different and patentably distinct methods because they involve different method steps, starting materials, reagents, and/or reaction conditions and/or produce different products or results. For example, Invention XI is drawn to a biosensor that comprise immobilized enzymes whereas the device of Invention IX does not.

6. The methods of Inventions I-VIII are each different and distinct from the database of Invention XII. They are different and patentably distinct inventions because they involve different method steps, starting materials, reagents, and/or reaction conditions and/or produce different products or results. For example, Inventions I-VIII are each drawn to methods that involve method steps, reagents, end results, etc. whereas Invention XII is a database (i.e. information) useable as a reference for calculations and analysis.

7. The devices and kit of Inventions IX-XI and the database of Invention XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together

and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Invention XII is drawn to a database (i.e. information) whereas the other three Inventions are apparatus, thus they have different modes of operation, function and effects.

8. Because these inventions are distinct for the reasons given above and
  - a. have acquired a separate status in the art as shown by their different classification;
  - b. have different and separately burdensome: manual and/or computer: structure, name and bibliographical searches; and
  - c. have divergent subject matter,restriction for examination purposes as indicated is proper.
9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynda T Guo whose telephone number is (703) 605-1200. The examiner can normally be reached on Mon - Fri (8:00am - 4:30pm).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on (703) 308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

*Lynda T Guo*  
Lynda T Guo  
Patent Examiner

*Reception*

November 7, 2002